8.0 PREMARKET NOTIFICATION 510(K) SUMMARY

Applicant:	Laura A. Worfolk, Ph.D. Pacific Hemostasis 11515 Vanstory Drive Huntersville, NC 28078 (704) 948-3276
Contact Person:	Same as above.
Date:	February 21, 2000
Trade Name:	Thrombostrate® Control Plasmas
Common Name:	Thrombostrate® Control Plasmas
Classification Name:	Plasma, Coagulation Control (per 21 CFR section 864.5425)
Equivalent Device:	Pacific Hemostasis Coagulation Control Plasma Level 1, #K984129

Description of Thrombostrate® Control Plasmas

Pacific Hemostasis Thrombostrate® is a set of five control plasmas with fibrinogen concentration ranging from low to high. All are lyophilized preparations of citrated plasma obtained from healthy donors. Stabilizers and buffers have been added to the plasmas prior to lyophilization. Each unit of source material used in the preparation of the reagent has been tested by an FDA approved method and found non-reactive for HBsAG and negative for antibodies to HIV and HCV.

Intended Use of Coagulation Control Level 1 (Normal)

Pacific Hemostasis Thrombostrate® Control Plasmas are intended for use as controls to monitor the performance of quantitative fibrinogen assays. Typical fibrinogen values are 30-60 mg/dL for Level 1, 70-120 mg/dL for Level 2, 208-304 mg/dL for Level 3, 360-440 mg/dL for Level 4 and 500-650 mg/dL for Level 5.

Summary of Performance Data for Substantial Equivalence Comparisons

Between-run and within-run precision studies yielded equivalent data for Thrombostrate® and Coagulation Control Plasma Level 1. For both controls a CV of less than 4% was obtained for between-run and within-run precision studies testing. Reconstituted stability studies performed at 2-8°C also indicated equivalent performance with less than a 5% change in recovered fibrinogen values obtained at 8 hours.

Conclusion

Pacific Hemostasis Thrombostrate® and Coagulation Control Level 1 have the same intended use, to monitor quantitative fibrinogen assays. Both are preparations of citrated plasma obtained from normal donors with added stabilizers and buffers. The performance data presented here, as well as the indistinguishable intended use and technological characteristics support the substantial equivalence claim for Pacific Hemostasis Thrombostrate® to Coagulation Control Level I. *Based on the data provided, it is our conclusion that these two products are substantially equivalent.*

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAR 2 4 2000

Laura A. Worfolk, Ph.D.
Principal Scientist
Pacific Hemostasis
11515 Vanstory Drive, Suite 125
Huntersville, North Carolina 28078-8144

Re: K000679
Trade Name: Thrombostrate® Control Plasmas
Regulatory Class: II
Product Code: GGN
Dated: February 21, 2000
Received: February 29, 2000

Dear Dr. Worfolk:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K000679

Device Name: Thrombostrate Control Plasmas

Indications for Use Form

Pacific Hemostasis Thrombostrate® Control Plasmas are intended for *in vitro* diagnostic use to monitor the performance of quantitative citrated plasma fibrinogen assays.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Peter E. Maher

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K000679

Prescription Use ✓ OR **Over-The-Counter Use** ___
(Per 21 CFR 801.109)

(Optional Format 1-2-96)